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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,588	03/09/2006	Taro Yoshikawa	126835	7199

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EXAMINER	
LAU, JONATHAN S	
ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,588	YOSHIKAWA ET AL.	
	Examiner	Art Unit	
	Jonathan S. Lau	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2009 and 20 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4 and 9-14* is/are pending in the application.

4a) Of the above claim(s) *11-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,9 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 19 May 2009 has been entered.

This Office Action is response to Applicant's Amendment and Remarks, filed on 19 May 2009, in which Applicant's Amendment and Remarks, filed on 20 Apr 2009, is entered, and claims 1, 3, 4, 9 and 10 are amended to change the scope and breadth of the claim and withdrawn claims 11-14 are amended.

This application is the national stage entry of PCT/JP04/11462, filed 10 Aug 2004; and claims benefit of foreign priority document JAPAN 2003-292135, filed 12 Aug 2003; currently an English language translation of this foreign priority document has not been filed.

Claims 1, 3, 4 and 9-14 are pending in the current application. Claims 11-14, drawn to non-elected inventions, are withdrawn. Claims 1, 3, 4, 9 and 10 are examined on the merits herein.

Rejections Withdrawn

Applicant's Amendment, filed 19 May 2009, with respect to claims 1, 3 , 4, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumagai et al. (US Patent Application Publication US 2002/0115622, published 22 Aug 2002, of record) in view of Koga et al. (Biol. Pharm. Bull., 2003, 26(9), p1299-1305, published online 06 Jun 2003, of record) and Mollica et al. (Journal of Pharmaceutical Sciences, 1978, 67(4), p443-465, of record) has been fully considered and is persuasive, as independent claims 1 and 10 as amended recite "An injectable pharmaceutical composition..." While the phrase "injectable pharmaceutical composition" is interpreted as an intended use, the composition of an ointment for topical administration taught by Kumagai et al. in view of the composition in the form for rectal administration taught by Koga et al. does not necessarily meet the structural limitations required by this intended use.

This rejection has been **withdrawn**.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Amended Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Upon further examination, the recitation "the concentration of cysteine is more than 70% after the composition is stored at 60 °C for 14 days" at claim 9 renders the claim indefinite because it is unclear what the 70% refers to. The concentration of cysteine is always 100% of cysteine concentration in the current composition. Therefore this limitation is given no patentable weight because it may necessarily always be met.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Amended Claims 1, 3, 4, 9 and 10 and rejected under 35 U.S.C. 103(a) as being unpatentable over Van Rossum et al. (Aliment. Pharmacol. Ther. 1998, 12, p199-205,

cited in PTO-892) in view of Chen et al. (US Patent Application Publication 2002/0147201, published 10 Oct 2002, cited in PTO-892).

Van Rossum et al. teaches glycerrhizin having anti-viral and hepatoprotective effects (abstract) in the form of Stronger Neo Minophagen C, a solution for intravenous use comprising of 2 mg/mL glycyrrhizin, 1 mg/mL cysteine, and 20 mg/mL glycine in physiological saline (page 203, left column, paragraph 1 in section Clinical Investigations), specifically noting the required elements of glycyrrhizin, glycine and cysteine. Van Rossum et al. teaches the composition administered at a dose of 80 mg glycyrrhizin daily (page 203, left column, paragraph 1 in section Clinical Investigations). Applicant provides evidence that Stronger Neo Minophagen C contains glycyrrhizin as monoammonium glycyrrhizin and cysteine as L-cysteine hydrochloride, and that Stronger Neo Minophagen C further comprises sodium sulfite (NPL citation 7 at IDS mailed 06 Jun 2006).

Van Rossum et al. does not specifically teach said injectable composition containing 8 to 16 mg/mL glycerrhizin, 3 to 6 mg/mL cysteine, and 80 to 160 mg/mL glycine wherein substantially no sulfite is contained in the composition (instant claim 1). Van Rossum et al. does not specifically teach said injectable composition containing 8 to 16 mg/mL monoammonium glycyrrhizin, 4 to 8 mg/mL cysteine hydrochloride, and 80 to 160 mg/mL glycine wherein substantially no sulfite is contained (instant claim 9).

Chen et al. teaches water soluble complexes comprising glycyrrhizin and an active agent (page 2, paragraph 19) including antiviral agents (page 2, paragraph 20). Chen et al. teaches said composition as a liquid for parenteral administration, or for

injection, also containing pharmaceutical excipients (page 3, paragraph 21). Chen et al. teaches preservatives such as sodium benzoate, sorbic acid, propionic acid, acetic acid, nitride and nitrates are known in the art as equivalent preservatives as sulfites within the art of the pharmaceutical compositions comprising glycyrrhizin taught by Chen et al. (page 6, paragraph 59). Chen et al. teaches said compositions containing glycyrrhizin soluble at an aqueous concentration of approximately 12.3 mg/mL (822.9 g/mol * 0.015 M) (figure 2 at drawing sheet 2 and page 9, paragraph 94) and 8.2 mg/mL (822.9 g/mol * 0.010 M) and 16.4 mg/mL (822.9 g/mol * 0.020 M) (figure 4 at drawing sheet 4).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Van Rossum et al. in view of Chen et al. Both Van Rossum et al. and Chen et al. are drawn to injectable compositions containing glycerrhizin having anti-viral activity. One of skill in the art would be motivated to increase the amount of glycyrrhizin, glycine and cysteine because Van Rossum et al. teaches the composition administered at a dose of 80 mg glycyrrhizin daily. One of skill in the art would be motivated to select a concentration of 8.2 mg/mL or 12.3 mg/mL because Chen et al. teaches water soluble complexes comprising that concentration of glycerrhizin. One of ordinary skill in the art would be motivated to increase the concetration of glycine and cysteine proportionately with the glycyrrhizin because Van Rossum et al. teaches glycine and cysteine play a physiological role. One of skill in the art would have a reasonable expectation of success to increase the concetration of glycine and cysteine proportionately with the glycyrrhizin because it is well known in the art that the amino acids glycine and cysteine are very soluble in water. It would have been *prima facie*

obvious to substitute sodium sulfite for another preservative to give a composition wherein substantially no sulfite is contained because Chen et al. teaches preservatives such as sodium benzoate, sorbic acid, propionic acid, acetic acid, nitride and nitrates are known in the art as equivalent preservatives as sulfites. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious, see MPEP 2144.06 II.

The property of the state of the composition after it is stored at 60 °C for 14 days (instant claim 9) is deemed to be an inherent property of the composition, and therefore necessarily present in the composition taught by Van Rossum et al. in view of Chen et al. See MPEP 2112.01 II, "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present.

Conclusion

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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